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Proposed Registration Decision

Ammonium Soap of Fatty Acid

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Overview

Proposed Registration Decision for Ammonium Soap of Fatty Acid

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is proposing full registration for the sale and use of Finalsan TGAI and two associated end-use products, Finalsan Concentrate and Finalsan Ready-to-Use, containing the technical grade active ingredient ammonium soap of fatty acid to control weeds, moss and algae in a variety of domestic sites. Ammonium soap of fatty acid is a lower risk biopesticide herbicide for domestic use.

An evaluation of available scientific information found that, under the approved conditions of use, the products have value and do not present an unacceptable risk to human health or the environment.

This Overview describes the key points of the evaluation, while the Science Evaluation provides detailed technical information on the human health, environmental and value assessments of Finalsan TGAI, Finalsan Concentrate and Finalsan Ready-to-Use.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[1] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its proposed conditions of registration. The Act also requires that products have value[2] when used according to label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (e.g. children) as well as organisms in the environment (e.g. those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the PMRA's website at www.pmra-arla.gc.ca.

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1 "Acceptable risks" as defined by subsection 2(2) of the *Pest Control Products Act*.

2 "Value" as defined by subsection 2(1) of the *Pest Control Products Act*: "the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (a) efficacy; (b) effect on host organisms in connection with which it is intended to be used; and (c) health, safety and environmental benefits and social and economic impact."

Before making a final registration decision on ammonium soap of fatty acid, the PMRA will consider all comments received from the public in response to this consultation document.[3] The PMRA will then publish a Registration Decision[4] on ammonium soap of fatty acid, which will include the decision, the reasons for it, a summary of comments received on the proposed final registration decision and the PMRA's response to these comments.

For more details on the information presented in this Overview, please refer to the Science Evaluation of this consultation document.

What Is Ammonium Soap of Fatty Acid?

Ammonium soap of fatty acid is a non-selective contact herbicide that does not translocate through the plant. The exact mechanism of necrosis is not completely understood, but it appears that ammonium soap of fatty acid causes a sudden drop in intracellular pH, which results in a loss of membrane integrity and rapid cell death.

Health Considerations

Can Approved Uses of Ammonium Soap of Fatty Acid Affect Human Health?

Ammonium soap of fatty acid is unlikely to affect your health when used according to label directions.

Potential exposure to ammonium soap of fatty acid may occur when handling and applying the products. When assessing health risks, two key factors are considered: the levels where no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (e.g. children and nursing mothers). Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

The technical grade active ingredient, ammonium soap of fatty acid, may cause eye irritation in animals. This warrants the signal words "WARNING—EYE IRRITANT" on the label of the end-use product Finalsan Concentrate and requires that goggles or a face shield be worn to avoid contact with eyes. The end-use product Finalsan Ready-to-Use contains a concentration of active ingredient that does not require goggles or a face shield.

Data on the specific technical grade active ingredient were limited; however, literature was available on similar compounds that did not indicate hazards that would be expected with the proposed use.

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[3] "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

[4] "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

Residues in Water and Food

Dietary risks from ammonium soap of fatty acid on food are not of concern.

Finalsan Concentrate and Finalsan Ready-to-Use are not applied directly to food, so residues on food are expected to be negligible.

Risks in Residential and Other Non-Occupational Environments

Residential risks are not of concern when Finalsan Concentrate and Finalsan Ready-to-Use are used according to label directions, which include protective measures.

Residential exposure to individuals mixing or applying the product is not expected to result in unacceptable risk when Finalsan Concentrate or Finalsan Ready-to-Use is used according to label directions.

Environmental Considerations

What Happens When Ammonium Soap of Fatty Acid Is Introduced Into the Environment?

Environmental risk associated with the use of ammonium soap of fatty acid is expected to be negligible.

Ammonium soap of fatty acid is non-persistent in aerobic soil and water. Under environmental conditions, fatty acids are expected to adsorb onto soil where they are rapidly biotransformed into carbon dioxide and water. Ammonium soap of fatty acid is therefore not expected to leach to groundwater.

Ammonium soap of fatty acid presents a negligible risk to wild mammals, birds, bees, fish and earthworms. As expected for a herbicide, ammonium soap of fatty acid is toxic to freshwater algae and aquatic plants. Based on the use pattern, however, a negligible amount of ammonium soap of fatty acid is expected to enter aquatic systems; therefore, risk to aquatic organisms is expected to be negligible.

Value Considerations

What Is the Value of Finalsan Concentrate and Finalsan Ready-to-Use?

Finalsan Concentrate and Finalsan Ready-to-Use are contact herbicides for domestic use in the control of weeds, moss and algae.

Ammonium soap of fatty acid, formulated as Finalsan Concentrate Herbicide (22.10%) and Finalsan Ready-to-Use Herbicide (3.68%), is a contact herbicide that controls weeds

within vegetable and flower gardens, landscaped areas, lawns, in the vicinity of small fruits and fruit trees, around and on buildings, sidewalks, fences, bark mulch, driveways, patios and gravel; and for the control of moss and algae around and on buildings, roofs, decks, sidewalks, fences, bark mulch, driveways, patios and gravel.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures being proposed on the labels of Finalsan Concentrate and Finalsan Ready-to-Use to address the potential risks identified in this assessment are as follows.

Human Health

Because there is a concern of eye irritation and the potential for inhalation toxicity, users must avoid getting the product in their eyes and avoid inhaling/breathing mist. Goggles or a face shield (protective eyewear) are required during mixing/handling of the active ingredient and Finalsan Concentrate.

Environment

The labels indicate not to contaminate irrigation or drinking water supplies or aquatic habitats by cleaning of equipment or disposal of wastes.

Next Steps

Before making a final registration decision on ammonium soap of fatty acid, the PMRA will consider all comments received from the public in response to this consultation document. The PMRA will accept written comments on this proposal up to 45 days from the date of publication of this document. Please forward all comments to Publications (contact information on the cover page of this document). The PMRA will then publish a Registration Decision, which will include its decision, the reasons for it, a summary of comments received on the proposed final registration decision and the Agency's response to these comments.

Other Information

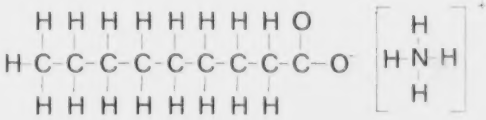
At the time the PMRA makes its registration decision, it will publish a Registration Decision on ammonium soap of fatty acid (based on the Science Evaluation of this consultation document). In addition, the test data referenced in this consultation document will be available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa).

Science Evaluation

Ammonium Soap of Fatty Acid

1.0 The Active Ingredient, Its Properties and Uses

1.1 Identity of the Active Ingredient

Active substance	Ammonium soap of fatty acid
Function	Herbicide
Chemical name	
1. International Union of Pure and Applied Chemistry (IUPAC)	Not provided
2. Chemical Abstracts Service (CAS)	Not provided
CAS Registry Number	84776-33-0
Molecular formula	$C_9H_{17}O_2$-$(NH_4)^+$
Molecular weight	178.03 g/mole
Structural formula	
Purity of the active ingredient	22.10% N (limits: 20.65–23.55%)

1.2 Physical and Chemical Properties of the Active Ingredients and End-Use Product

Technical Product—Finalsan TGAI

Property	Result
Colour and physical state	Pale yellow liquid
Odour	Ammonia
Melting range	Not applicable
Boiling point or range	100°C
Density	1.004 ± 0.002 g/mL

Property	Result
Vapour pressure at 20°C	Not applicable as the product is a salt
Ultraviolet (UV)—visible spectrum	Not expected to absorb UV
Solubility in water at 20°C	The product is miscible with water in all proportions
Solubility in organic solvents at 20°C (g/100 mL)	Soluble in acetone Immiscible in all proportions with diethyl ether and hexanes
n-Octanol–water partition coefficient (K_{ow})	Not applicable as the product is miscible in all proportions with water
Dissociation constant (p*K*a)	Not provided
Stability (temperature, metal)	Relatively stable with aluminum and stainless steel; reacts with brass, galvanized metal, zinc and copper

End-Use Product—Finalsan Concentrate

Property	Result
Colour	Pale yellow
Odour	Distinct ammonia odour
Physical state	Liquid
Formulation type	Solution
Guarantee	22.10% N (limits: 20.65–23.55%)
Container material and description	High density polyethylene (HDPE) bottles
Density	1.004 g/mL at 20°C
pH of 1% dispersion in water	8.4
Oxidizing or reducing action	The product is neither an oxidizing nor a reducing agent.
Storage stability	Stable for at least two years in HDPE containers
Corrosion characteristics	Relatively stable with aluminum and stainless steel; reacts with brass, galvanized iron, zinc and copper
Explodability	Not explosive

End-Use Product—Finalsan Ready-to-Use

Property	Result
Colour	Colourless
Odour	Slight ammonia odour
Physical state	Liquid
Formulation type	Solution
Guarantee	3.68% N (limits: 3.50–3.86%)
Container material and description	HDPE bottles
Density	0.994 g/mL at 20°C
pH of 1% dispersion in water	7.85
Oxidizing or reducing action	The product is neither an oxidizing nor a reducing agent.
Storage stability	Stable for at least two years in HDPE containers
Corrosion characteristics	Relatively stable with aluminum and stainless steel; reacts with brass, galvanized iron, zinc and copper
Explodability	Not explosive

1.3 Directions for Use

Finalsan Concentrate and Finalsan Ready-to-Use are non-selective contact herbicides for the control of weeds within vegetable and flower gardens, landscaped areas, lawns, in the vicinity of small fruits and fruit trees, around and on buildings, sidewalks, fences, bark mulch, driveways, patios, and gravel; and for the control of moss and algae around and on buildings, roofs, decks, sidewalks, fences, bark mulch, driveways, patios, and gravel. As there is no translocation of ammonium soap of fatty acid in the plant, multiple applications are necessary to control regrowth of perennial and biennial weeds, and later flushes of annual weeds. Since ammonium soap of fatty acid is a non-selective herbicide, care must be taken to avoid spraying desirable plants. Injury will occur to any plant part contacted. Application rates and water volumes for Finalsan Concentrate and Finalsan Ready-to-Use can be found in Table 1.3.1.

Table 1.3.1 Use Patterns for Finalsan Concentrate (22.10% ammonium soap of fatty acid) and Finalsan Ready-to-Use (3.68% ammonium soap of fatty acid)

Pest Claim	Herbicide Rate	Application Volume	Specific Instructions
Finalsan Concentrate			
Weeds	1 part Finalsan Concentrate to 5 parts water (200 mL to 1 L water)	100–200 mL/m^2	• For annual weeds, use at the lower rate; for perennial and more established weeds, use at the higher rate • Thorough coverage is extremely important • Repeat treatment every 2–3 weeks to control new weeds growing from seed and regrowth from biennial and perennial weeds • When spot treating individual weeds in lawns, avoid spraying surrounding grass, as injury will occur.
Moss and algae	1 part Finalsan Concentrate to 19 parts water (55 mL to 1 L water)	100–500 mL/m^2	• One application may control moss for up to one year • Thorough coverage is extremely important
Finalsan Ready-to-Use			
Weeds	3.68%	Spray weeds thoroughly	• Thorough coverage is extremely important • Repeat treatment every 2–3 weeks to control new weeds growing from seed and regrowth from biennial and perennial weeds • When spot treating individual weeds in lawns, avoid spraying surrounding grass, as injury will occur.
Moss and algae	3.68%	Spray moss and algae thoroughly	• One application may control moss for up to one year • Thorough coverage is extremely important

1.4 Mode of Action

Ammonium soap of fatty acid is a non-selective contact herbicide that does not translocate through the plant. The exact mechanism of necrosis is not completely understood, but it appears that the ammonium soap of fatty acid causes a sudden drop in intra-cellular pH, which results in a loss of membrane integrity and rapid cell death.

2.0 Methods of Analysis

2.1 Methods for Analysis of the Active Ingredient

The methods provided for the analysis of the active ingredient and the impurities in Finalsan Technical have been validated and assessed to be acceptable.

2.2 Method for Formulation Analysis

The method provided for the analysis of the active ingredient in the formulations has been validated and assessed to be acceptable for use as an enforcement analytical method.

2.3 Methods for Residue Analysis

Not required.

3.0 Impact on Human and Animal Health

3.1 Toxicology Summary

Acute toxicity studies were conducted at concentrations above those of the proposed products. Finalsan Concentrate is considered to be of low toxicity by the oral and dermal routes and via inhalation. The inhalation study was tested at a higher concentration (36.8%) than the concentrate (22.1%) without any effects at doses up to 1.66 mg/L. Finalsan Concentrate is considered moderately irritating to the eye and minimally irritating to the skin. Finalsan Concentrate is not a dermal sensitizer. See Appendix I, Table 1.

Finalsan Ready-to-Use is mildly irritating to the eye and minimally irritating to the skin. See Appendix I, Table 1.

Short-term, long-term and special studies (including developmental and genetic toxicology studies) were not provided. A rationale was provided to have the requirement for these studies waived. The waiver request is based on a) the natural occurrence of both ammonia and fatty acids; b) occurrence in many common foods and consumption in the average human diet; c) requirement of nitrogen as a macronutrient essential to plant and animal growth; d) the rapid degradation of ammoniated soap of fatty acids; e) known metabolic pathways and documentation in the literature; f) known toxicology of salts of fatty acids; g) exemption from

the requirement of a tolerance by the United States Environmental Protection Agency (USEPA) of the active ingredients ammoniated soap of fatty acids; and h) the intended use pattern does not include application to food crops. The waiver request was considered acceptable (Appendix I, Table 2).

No published literature was presented by the applicant to specifically address the potential for subchronic or chronic toxicity.

A qualitative description of the metabolism of fatty acids and ammonia was provided. The initial breakdown process of the ammonium soap of fatty acid is the division of the soap into ammonium and fatty acid ions. Ingestion of ammonium soap of fatty acid will release nonanoic fatty acid (C9) in the gut.

Fatty acids are part of the normal metabolic makeup of cells, and the enzymatic pathways for their degradation and synthesis are well established in the literature.

Although the relevance of the data provided in published literature and the USEPA Reregistration Eligibility Decision (RED) on this active ingredient may be limited, it does provide some information on similar available compounds.

In the USEPA RED, a reproduction study on potassium cocoa fatty acid (soap) was referenced. Mice and rats were treated dermally (not occluded or washed) with 0.3%, 3.0% and 30.0% soap solution. A point to be noted in considering effects from this study was that dosing was after mating (days 2–13 in mice; days 2–15 in rats). Local reactions on the skin and/or irritability and hypersensitivity were noted in animals treated with soap at 3% and 30%. Weight loss or marked reduction of body-weight gain was observed in mice at 3% and 30%. A decrease in the number of litters with viable young (from non-pregnancy and/or total litter loss) in mice was considered a further manifestation of maternal toxicity. As stated in the USEPA RED, due to negligible numbers of litters and young available for examination, assessment in mice was impossible at 30% and doubtful at 3%. The USEPA RED reported an increased incidence of musculoskeletal system abnormalities in mice at 30%. There appeared to be an increased incidence of cervical ribs; however, it was difficult to determine whether this effect was treatment-related due to the lack of viable young at 30% and presence of maternal toxicity.There were no treatment-related effects noted in the rat.

In the USEPA RED, "DNA inhibition" was reported with sodium salt of caprylic acid (medium length carbon chain) and unscheduled DNA synthesis was found in oleic acid mutagenicity studies. These studies were not performed on the same active ingredient for which registration is sought.

In one published document, oleic acid was referred to as a tumor promoter that induced mitotic aneuploidy in yeast..

In another published document, oleic acid was tested for elimination of metabolic cooperation, cellular toxicity, mutagenicity and the induction of chromosomal changes, including sister chromatid exchanges in V79 cells. Oleic acid was non-cytotoxic up to 10 µg/mL but did induce

tetraploidy and the numerical chromosome changes in a non-dose-related manner. It should be noted that there are concerns with the study method and results. Oleic acid was not mutagenic in its own right.

Neurotoxicity studies were not provided. A rationale was provided to have these requirements waived. Based on the available literature at the time of evaluation, neurotoxic effects are not anticipated and the waiver is accepted.

Data on the specific technical grade active ingredient was limited; however, literature was available on similar compounds that did not indicate hazards that can not be mitigated.

In order to mitigate any concerns, precautionary statements have been added to the product labels to limit exposure. Eye irritation via exposure to the concentrate can be mitigated with the addition of labelling requiring goggles or a face shield during mixing and handling of the concentrate. Although an argument was presented that the spray mist will not persist in air due to the droplet size, a precautionary statement to avoid inhaling the product was added to mitigate any potential concern of inhalation toxicity. The addition of a precautionary inhalation statement addresses the fact that the inhalation toxicity study was not tested up to the limit dose. Oral exposure is expected to be minimal due to the non-food use scenario as well the product having an unpleasant taste.

A qualitative risk assessment was conducted since risk could not be characterized quantifiably.

3.1.1 PCPA Hazard Characterization

As a quantitative risk assessment was not conducted, a PCPA factor is not required.

3.2 Determination of Acute Reference Dose

As these products are not intended for food use, an acute reference dose is not required.

3.3 Determination of Acceptable Daily Intake

As these products are not intended for food use, an acceptable daily intake is not required.

3.4 Occupational and Residential Risk Assessment

3.4.1 Toxicological Endpoints

A qualitative risk assessment was conducted since risk could not be characterized quantifiably.

3.4.2 Dermal Absorption

Dermal absorption is not expected to be of concern.

3.4.3 Occupational Exposure and Risk

There is no potential for occupational exposure since these products are for domestic use.

3.4.4 Residential Exposure and Risk Assessment

Residential exposure to Finalsan Concentrate is expected to be short-term during mixing of the concentrate and application of the dilution. Residential exposure to Finalsan Ready-to-Use is expected to be short-term during application of the product. Finalsan Concentrate and Finalsan Ready-to-Use may be applied within vegetable and flower gardens, landscaped areas, lawns, in the vicinity of small fruits and fruit trees, around and on buildings, roofs, decks, sidewalks, fences, bark mulch, driveways, patios and gravel. They may be applied by hand-held trigger sprayer, hand sprayer, backpack sprayer or hose-end sprayer. The products are non-selective, which would suggest broadcast spray for surfaces such as buildings and roofs (e.g. hose-end application), but they would need to be applied by hand-held trigger around non-target plants. There can be up to four applications per season.

Oral exposure is expected to be minimal due to the non-food use scenario. In addition, the USEPA RED stated that oral exposure to soaps is self-limiting due to the easily recognized and unpleasant taste. The applicant provided the uncited argument that spray mist will result when plants are treated but not persist in the air because of its low vapour pressure and because the spray mist is denser than air.

The applicant requested a waiver of the exposure requirements for Finalsan Concentrate. The waiver request is based on the following: a) exposure is limited when used according to label directions; b) the product is diluted before it is sprayed; c) the product does not present a toxicological hazard; d) the product degrades rapidly in the environment; e) the product has a low application area (homeowner use only); and f) ammonium soaps of fatty acids have been used for many years without exhibiting cause for concern. The waiver request was considered acceptable.

Residential exposure to individuals mixing or applying the product is not expected to result in unacceptable risk when Finalsan Concentrate or Finalsan Ready-to-Use is used according to label directions.

As well, exposure to bystanders (including children and companion animals) is expected to be negligible when the product is used according to label directions.

3.5 Food Residues Exposure Assessment

Finalsan Concentrate and Finalsan Ready-to-Use are not applied directly to food. The risk from dietary exposure is considered negligible, so a food residue exposure assessment was not required.

4.0 Impact on the Environment

4.1 Fate and Behaviour in the Environment

Finalsan TGAI (ammonium soap of fatty acid) is soluble in water and will not bioaccumulate. Based on the vapour pressure (1.6×10^{-3} mm Hg) and Henry's law constant (1.6×10^{-6} atm $\times$ m^3/mol), nonanoic acid (the main fatty acid and organic constituent of Finalsan TGAI) is expected to be slightly volatile from water surface and moist soil. However, ammonium soap of fatty acid is not expected to be volatile.

With an estimated K_{oc} of 1700, nonanoic acid has low soil mobility. Under environmental conditions, fatty acids, the organic components of Finalsan TGAI, are expected to adsorb onto charged soil micelles where they are rapidly biotransformed into carbon dioxide and water with a half-life of less than one day. The ammonium component is expected to transform through the nitrogen cycle.

Under most Canadian conditions, accumulation of ammonium soap of fatty acid in soil or contamination in surface water from the use of Finalsan Concentrate and Finalsan Ready-to-Use is expected to be negligible based on the use pattern.

Data on the fate and behaviour of ammonium soap of fatty acid are summarized in Appendix I, Table 3.

4.2 Effects on Non-Target Species

Based on the low toxicity, use pattern and rapid microbial degradation of the active ingredient, a qualitative risk characterization was conducted.

4.2.1 Effects on Terrestrial Organisms

Risk of ammonium soap of fatty acid to terrestrial organisms was based upon evaluation of toxicity data for one mammal and three bird species representing vertebrates (acute oral and acute dietary exposure), one bee species and one earthworm species representing invertebrates (acute exposure), and six crop species representing plants (short-term exposure). Waiver requests for data requirements of chronic studies were accepted based on the fact that ammonium soap of fatty acid is rapidly degraded (half-life < 1 day) by microbial action.

Ammonium soap of fatty acid generally showed low toxicity to terrestrial organisms; it was relatively non-toxic to earthworms, bees, birds and small mammals. Therefore, risk to these terrestrial organisms is negligible. Ammonium soap of fatty acid showed some phytotoxic effects on plants. The directions for use on the product labels of Finalsan Concentrate and Finalsan Ready-to-Use indicate that a thorough coverage on weeds is extremely important. Since the product will be applied by spot treatment or by using a coarse nozzle setting to reduce drift, it is unlikely that non-targets plants will get coated by the product as a result of the proposed use.

Also, the product label includes a warning statement to avoid spraying desirable plants. The use of Finalsan Concentrate and Finalsan Ready-to-Use following label directions will therefore result in negligible risk to non-target terrestrial plants. Data for terrestrial organisms, including invertebrates, are summarized in Appendix I, Table 4.

4.2.2 Effects on Aquatic Organisms

Risk to aquatic organisms was based upon evaluation of acute toxicity data for seven freshwater species (one invertebrate, two fish, three algae and one vascular plant). There were no data for estuarine/marine species.

Ammonium soap of fatty acid generally showed low toxicity to aquatic organisms; it was slightly toxic to *Daphnia* and non-toxic to rainbow trout and golden ide. Ammonium soap of fatty acid showed adverse effects to freshwater algae and aquatic vascular plants. Because of the use pattern (spot treatment or broadcast application using a hand-held trigger sprayer, hand sprayer, backpack sprayer or hose-end sprayer) and rapid biotransformation, exposure to aquatic organisms will be minimal. Therefore, negligible risk is expected. Data for aquatic organisms, including invertebrates, are summarized in Appendix I, Table 4.

5.0 Value

5.1 Effectiveness Against Pests

The data package provided in support of Finalsan Concentrate and Finalsan Ready-to-Use consisted of 15 trials conducted in Canada with Finalsan Concentrate and Finalsan Ready-to-Use; three American trials using H01 RTU or H01 Concentrate (active ingredient ammonium soap of fatty acid at 3.68% or 22%, respectively); and 33 trials conducted in 17 locations in Germany using Finalsan and Finalsan AF (Pelargonic acid at 186.7g a.i./L and 33g a.i./L, respectively). Control of annual and perennial weeds, as well as of moss and algae, was evaluated. Trials included all proposed treatments. Efficacy was assessed as percent control when compared to an untreated check at one to three intervals throughout the test period. Weed control was also evaluated after multiple applications.

5.1.1 Acceptable Efficacy Claims

The submitted efficacy data were sufficient to determine the lowest effective rate for Finalsan Concentrate and Finalsan Ready-to-Use, and to support the pest claims summarized in Table 5.1.1.1.

Table 5.1.1.1 Efficacy Claims for Finalsan Concentrate and Finalsan Ready-to-Use Herbicide

Herbicide Rate	Pests Controlled
Finalsan Concentrate	
1 part Finalsan Concentrate to 5 parts water (200 mL in 1 L of water) in 100–200 mL/m^2; repeat treatment every 2–3 weeks	Annual and perennial grass and broadleaf weeds
1 part Finalsan Concentrate to 19 parts water (55 mL in 1 L of water) in 100–500 mL/m^2; one application may control moss for up to 1 year	Moss and algae
Finalsan Ready-to-Use	
Spray weeds thoroughly; repeat treatment every 2–3 weeks.	Annual and perennial grass and broadleaf weeds
Spray moss and algae thoroughly; one application may control moss for up to 1 year.	Moss and algae

5.2 Phytotoxicity to Host Plants

Finalsan Concentrate and Finalsan Ready-to-Use are to be used within vegetable and flower gardens, landscaped areas, lawns, in the vicinity of small fruits and fruit trees, around and on buildings, sidewalks, fences, bark mulch, driveways, patios and gravel. No crop tolerance data were provided, as ammonium soap of fatty acid is not to be applied to any desirable plant. Both labels have a warning to "avoid spraying desirable plants." In addition, the following statement was added:

"When spot treating individual weeds in lawns, avoid spraying the surrounding grass (lawn) as injury will occur."

5.3 Impact on Succeeding Crops

Not applicable.

5.3.1 Acceptable Claims for Rotational Crops

Not applicable.

5.4 Economics

The economic viability of this soap-based herbicide is dependent on the need to replace synthetic herbicides with herbicides that have low mammalian/environmental toxicity.

5.5 Sustainability

5.5.1 Survey of Alternatives

The alternate chemical controls recommended for the pests controlled by Finalsan Concentrate and Finalsan Ready-to-Use include glufosinate, glyphosate, paraquat and diquat.

Manual removal of weeds constitutes non-chemical control.

5.5.2 Compatibility With Current Management Practices Including Integrated Pest Management

Finalsan Concentrate and Finalsan Ready-to-Use are compatible with current management practices including integrated pest management because they are a less toxic, non-synthetic method of pest control.

5.5.3 Information on the Occurrence or Possible Occurrence of the Development of Resistance

Ammonium soap of fatty acid is not a poison but causes a sudden drop in intracellular pH, which results in a loss of membrane integrity and rapid cell death. Resistance to this mode of action would not be expected to occur.

5.5.4 Contribution to Risk Reduction and Sustainability

Finalsan Concentrate and Finalsan Ready-to-Use are contact herbicides with no residual activity. After they have been sprayed, the liquid dries on the plant parts and starts to degrade. The products of degradation are N, CO_2, and H_2O, all of which are ubiquitous in nature.

6.0 Pest Control Product Policy Considerations

6.1 Toxic Substances Management Policy Considerations

The management of toxic substances is guided by the federal government's Toxic Substances Management Policy (TSMP), which puts forward a preventive and precautionary approach to deal with substances that enter the environment and could harm the environment or human health. The policy provides decision makers with direction and sets out a science-based management framework to ensure that federal programs are consistent with its objectives. One of the key management objectives is virtual elimination from the environment of toxic substances that result predominantly from human activity and that are persistent and bioaccumulative. These substances are referred to in the policy as Track 1 substances.

During the review process, ammonium soap of fatty acid was assessed in accordance with PMRA Regulatory Directive DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*. Substances associated with the use of ammonium soap of fatty acid were also considered, including transformation products formed in the environment, and contaminants and formulants in the technical product and the end-use product. Ammonium soap of fatty acid and its transformation products were evaluated against the following Track 1 criteria: persistence in soil ≥ 182 days; persistence in water ≥ 182 days; persistence in sediment ≥ 365 days; persistence in air ≥ 2 days; bioaccumulation log K_{ow} ≥ 5 (or bioaccumulation factor ≥ 5000). In order for ammonium soap of fatty acid or its transformation products to meet Track 1 criteria, the criteria for both bioaccumulation and persistence (in one media) must be met. The technical product and end-use product, including formulants, were assessed against the contaminants identified in the *Canada Gazette*, Part II, Volume 139, Number 24, pages 2641–2643: *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern, Part 3, Contaminants of Health or Environmental Concern*. The PMRA has reached the following conclusions:

- Ammonium soap of fatty acid does not meet the Track 1 criteria and will not form any transformation products that meet the Track 1 criteria. The half-life of this fatty acid in soil is less than one day. In water, ammonium soap of fatty acid is also expected to be rapidly transformed. Ammonium soap of fatty acid is not expected to be bioaccumulative. The octanol–water partition coefficient (log K_{ow}) of nonaoic acid (the main organic component of ammonium soap of fatty acid) is 3.42, which is below the TSMP Track 1 cut-off criterion of ≥5.0. The ammonium soap of fatty acid is expected to have a lower log K_{ow} than the nonanoic acid.
- There are no Track 1 formulants in the technical product or end-use products.
- There are no Track 1 contaminants in the technical product or end-use products.

6.2 Formulants and Contaminants of Health or Environmental Concern

During the review process, formulants and contaminants in the technical product and end-use products are assessed against the formulants and contaminants identified in the *Canada Gazette*, Part II, Volume 139, Number 24, pages 2641–2643: *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern*. This list of formulants and contaminants of health and environmental concern are identified using existing policies and regulations, including the following:

- the federal Toxic Substances Management Policy
- the Ozone-depleting Substance Regulations, 1998, of the *Canadian Environmental Protection Act* (substances designated under the Montreal Protocol)
- the PMRA Formulants Policy as described in PMRA Regulatory Directive DIR2006-02, *Formulants Policy and Implementation Guidance Document*

The *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* is maintained and used as described in the PMRA Notice of Intent NOI2005-01, *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern under the New Pest Control Products Act*.

The *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* consists of three parts:

- Part 1: Formulants of Health or Environmental Concern
- Part 2: Formulants of Health or Environmental Concern that are Allergens Known to Cause Anaphylactic-Type Reactions
- Part 3: Contaminants of Health or Environmental Concern

The contaminants to which Part 3 applies meet the federal TSMP criteria as Track 1 substances, and are considered in Section 6.1. The following assessment refers to the formulants and contaminants in Parts 1 and 2 of the list.

- Technical grade ammonium soap of fatty acid and the end-use products Finalsan Concentrate and Finalsan Ready-to-Use do not contain any formulants or contaminants of health or environmental concern identified in the *Canada Gazette*, Part II, Volume 139, Number 24, pages 2641–2643: *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern*.

7.0 Summary

7.1 Human Health and Safety

Data on the specific technical grade active ingredient was limited; however, literature was available on similar compounds that did not indicate hazards that can not be mitigated with label amendments for additional personal protective equipment.

In order to mitigate any concerns, precautionary statements have been added to the product labels to limit exposure. Eye irritation via exposure to the concentrate can be mitigated with the addition of labelling requiring goggles/face shield during the mixing/handling of the concentrate. Although an argument was presented that the spray mist will not persist in air due to the droplet size, a precautionary statement to avoid inhaling the product was added to mitigate any potential concern of inhalation toxicity. The addition of a precautionary inhalation statement addresses the fact that the inhalation toxicity study was not tested up to the limit dose. Oral exposure is expected to be minimal due to the non-food use scenario as well the product having an unpleasant taste.

7.2 Environmental Risk

Ammonium soap of fatty acid is expected to be non-persistent in terrestrial and aquatic environments. Biotransformation in aerobic conditions is the principal route of dissipation. Ammonium soap of fatty acid is immobile in soil and is not expected to leach into groundwater. No major transformation products are expected to occur in the environment.

The proposed use of ammonium soap of fatty acid will have a negligible impact on birds, mammals and aquatic organisms. It should be noted that ammonium soap of fatty acid is harmful to terrestrial and aquatic plants. The precautionary statement on the product label reads as follows: "Avoid spraying desirable plants. Avoid direct application to ponds, streams and lakes."

7.3 Value

The data submitted to support the registration of Finalsan Concentrate and Finalsan Ready-to-Use are adequate to describe its efficacy for use within vegetable and flower gardens, landscaped areas, lawns, in the vicinity of small fruits and fruit trees, around and on buildings, sidewalks, fences, bark mulch, driveways, patios and gravel for the control of weeds, moss, and algae. Finalsan Concentrate and Finalsan Ready-to-Use will cause necrosis to plants directly contacted by the products. Therefore, warning statements appear on the labels to mitigate injury to desirable plants.

7.4 Unsupported Uses

Certain uses originally proposed by the applicant with this submission are not supported by the PMRA either because value has not been adequately demonstrated or because of unacceptable risk. Unsupported uses are outlined in Appendix I, Table 5.

8.0 Proposed Regulatory Decision

Health Canada's PMRA, under the authority of the *Pest Control Products Act*, is proposing full registration for the sale and use of Finalsan TGAI and two associated end-use products, Finalsan Concentrate and Finalsan Ready-to-Use, containing the technical grade active ingredient ammonium soap of fatty acid to control weeds, moss and algae in a variety of domestic sites. An evaluation of current scientific data from the applicant as well as scientific reports and information from other regulatory agencies has resulted in the determination that, under the proposed conditions of use, the end-use products have value and do not present an unacceptable risk to human health or the environment.

List of Abbreviations

a.i.	active ingredient
ALS	acetolactate synthase
atm	atmosphere(s)
bw	body weight
d	day(s)
DNA	deoxyribonucleic acid
EP	end-use product
g	gram(s)
ha	hectare(s)
HDPE	high density polyethylene
Hg	mercury
kg	kilogram(s)
K_{oc}	organic-carbon partition coefficient
K_{ow}	*n*-octanol–water partition coefficient
L	litre(s)
LC_{50}	lethal concentration to 50%
LD_{50}	lethal dose to 50%
m^3	metre(s) cubed
mg	milligram(s)
mm	millimetre(s)
mL	millilitre(s)
MAS	maximum average score
NOEC	no observed effect concentration
NOEL	no observed effect level
PCPA	*Pest Control Products Act*
PMRA	Pest Management Regulatory Agency
TSMP	Toxic Substances Management Policy
USEPA	United States Environmental Protection Agency
UV	ultraviolet

Appendix I Tables and Figures

Table 1 Acute Toxicity of Ammonium Soap of Fatty Acid and Its Associated End-Use Products (Finalsan Concentrate and Finalsan Ready-to-Use)

Study Type	Species	Result	Comment	Reference (PMRA #)
Acute Toxicity of Finalsan Concentrate				
Oral	Rat	LD_{50} > 5000 mg/kg bw	Low toxicity	1280521
Dermal	Rat	LD_{50} > 5000 mg/kg bw	Low toxicity	1280522
Inhalation	Rat	LC_{50} > 1.66 mg/L	Slightly toxic	1280523
Skin irritation	Rabbit	MAS = 1.2[a]	Minimally irritating	1280528
Eye irritation	Rabbit	MAS = 35.6[a]	Moderately irritating	1280524, 1280526
Skin sensitization	Guinea pig	Not a dermal sensitizer	Not a dermal sensitizer	1280529
Acute Toxicity of End-Use Product—Finalsan Ready-to-Use				
Skin irritation	Rabbit	MAS = 0.11[a]	Minimally irritating	1286842
Eye irritation	Rabbit	MAS = 18.06[a]	Mildly irritating	1286838

[a] MAS = maximum average score for 24, 48 and 72 hours

Table 2 Toxicity Profile of Technical Ammonium Soap of Fatty Acid

Study Type	Species	Results	Reference
No studies on the technical grade active ingredient were provided; however, a waiver rationale was submitted and accepted.			

Table 3 Fate and Behaviour in the Environment

Property	Test Substance	Value	Comment	Reference (PMRA #)
Transformation in terrestrial system				
Abiotic transformation				
Hydrolysis	Potassium salts of fatty acids	No hydrolysis occurred over 43 days	Stable	1406269
Phototransformation in air Reaction involving photochemically produced hydroxyl radicals from the atmosphere	Nonanoic acid	Atmospheric half-life of 1.6 days	Non-persistent	1588847

Property	Test Substance	Value	Comment	Reference (PMRA #)
Biotransformation				
Biotransformation in aerobic soil	Fatty acids	Half-life < 1 day	Non-persistent	1406269
Biotransformation in aerobic soil Study carried out on two German aerobic soils: Sandfeld (loamy sand soil; pH 5.2, organic carbon 0.8%) and Eisengrund (sandy loam soil; pH 7.4, organic carbon 1.7%). The test system consisted of a series of 250 mL Erlenmeyer flasks spiked with a Neudosan standard.	Neudosan (47% potassium salts of fatty acids)	Half-life of 3 days	Rapid biotransformation (evolved CO_2 and volatile organics were not determined)	1280534
Mobility				
Adsorption/desorption in soil	Nonanoic acid	K_{oc} = 1700	Low mobility	1588847
Transformation in aquatic system				
Abiotic transformation				
Hydrolysis	Potassium salts of fatty acids	No hydrolysis occurred over 43 days	Stable	1406269
Biotransformation				
Biotransformation in aerobic water/sediment systems	Ammonium soap of fatty acid	Waiver accepted; expected half-life < 1 day	Biotransformation of fatty acids in water is expected to be similar to that in soil. Rapid biotransformation is expected.	1280533

Table 4 Toxicity to Non-Target Species

Effects on Terrestrial Organisms					
Organism	**Exposure**	**Test Substance**	**Endpoint Value**	**Degree of Toxicity[a]**	**Reference (PMRA #)**
Invertebrates					
Earthworm	Acute	NEU1170 H guarantee: 21% ASFA*	14-d NOEC: 210 mg a.i./kg (or 1000 mg EP/kg) 14-d LC_{50} > 210 mg a.i./kg (or >1000 mg EP/kg)		1280537

Effects on Terrestrial Organisms					
Organism	**Exposure**	**Test Substance**	**Endpoint Value**	**Degree of Toxicity[a]**	**Reference (PMRA #)**
Bee	Oral	NEU1170 H guarantee: 22% ASFA	48-h LD_{50} > 108.94 µg a.i./bee NOEC: 25 µg a.i./bee	Non-toxic	1280538
	Contact	NEU1170 H guarantee: 22% ASFA	48-h LD_{50} > 100 µg a.i./bee NOEC: 25 µg a.i./bee	Non-toxic	1280538
Birds					
Bobwhite quail	Acute	Neudosan Neu guarantee: 49% PSFA*	NOEL: 2450 mg a.i./kg bw (or 5000 mg EP/kg bw) LD_{50} > 2450 mg a.i./kg bw (or >5000 mg EP/kg bw)	Practically non-toxic	1280544
	Dietary	Neudosan Neu guarantee: 49% PSFA	5-d NOEC: 2450 mg a.i./kg diet (or 5000 mg EP/kg diet 5-d LC_{50} > 2450 mg a.i./kg diet (or >5000 mg EP/kg diet)	Non-toxic (based on EP)	1280543
Mallard duck	Dietary	Neudosan Neu guarantee: 49% PSFA	5-d NOEC: 2450 mg a.i./kg diet (or 5000 mg EP/kg diet) 5-d LC_{50} > 2450 mg a.i./kg diet (or >5000 mg EP/kg diet)	Non-toxic (based on EP)	1280546
Japanese quail	Dietary	NEU 1170H guarantee: 22% ASFA	5-d NOEC: 1100 mg a.i./kg diet (or 5000 mg EP/kg diet) 5-d LC_{50} > 1100 mg a.i./kg diet (or >5000 mg EP/kg diet)	Non-toxic (based on EP)	1280545
Mammals					
Rat	Acute	NEU 1170H guarantee: 36.8% ASFA	LD_{50} > 5000 mg EP/kg bw	Non-toxic (based on EP)	1280536
Vascular plants					
Vascular plant	Vegetative vigour	NEU 1170H guarantee: 22% ASFA	EC_{25}: 6.753 g a.i./ha (tomato) NOEC: 365 g a.i./ha based on phytotoxicity	Phytotoxic effects at >365 g a.i./ha	1280549

[a] Atkins et al. (1981) for bees and USEPA classification for others, where applicable.

* ASFA: ammonium soap of fatty acid; PSFA: potassium salts of fatty acids.

Effects on Aquatic Organisms					
Organism	**Exposure**	**Test Substance**	**Endpoint Value**	**Degree of Toxicity[a]**	**Reference (PMRA #)**
Freshwater species					
Daphnia magna	Acute	NEU 1170H guarantee: 22% *ASFA	48-h NOEC: 2.9 mg a.i./L 48-h EC_{50}: 26.2 mg a.i./L	Slightly toxic	1280539
Rainbow trout	Acute	NEU 1170 H guarantee: 22.1% ASFA	96-h NOEC: 15.2 mg a.i./L 96-h LC_{50} > 15.2 mg a.i./L	Non-toxic at highest concentration tested	1280540
Golden ide (*Leuciscus idus)*	Acute	NEU 1170 H guarantee: 22.1% ASFA	96-h NOEC: 8.02 mg a.i./L 96-h LC_{50} > 8.02 mg a.i./L	Non-toxic at highest concentration tested	1280541
Green algae (*Scenedesmus subspicatus*)	Acute	NEU 1170H guarantee: 22% ASFA	72-h NOEC: 0.44 mg a.i./L 72-h EC_{50}: 16.8 mg a.i./L (cell density) 72-h NOEC: 4.4 mg a.i./L 72-h EC_{50}: 114.5 mg a.i./L (growth rate)		1280547
Blue-green algae (*Anabaena flos-aquae*)	Acute	NEU 1170H guarantee: 22.1 % ASFA	96-h NOEC: 7.2 mg a.i./L 96-h EC_{50} > 7.2 mg a.i./L	No adverse effects at highest test concentration	1280548
Vascular plant	Dissolved	NEU 1170H guarantee: 22% ASFA	7-d NOEC: 11 mg a.i./L (phytotoxic effects—pale discoloration) 7-d EC_{50}: 11.3 mg a.i./L (biomass) 7-d EC_{50}: 18.4 mg a.i./L (frond number)		1280550

[a] USEPA classification, where applicable.

* ASFA: ammonium soap of fatty acids.

Table 5 Use (label) Claims Proposed by Applicant and Whether Acceptable or Unsupported

Applicant-Proposed Label Claims	Accepted Label Claims	Unsupported Label Claims and Comments
For use on weeds within vegetable and flower gardens, landscaped areas, lawns, in the vicinity of small fruit and fruit trees, around and on buildings, sidewalks, fences, bark mulch, driveways, patios and gravel	For use on weeds within vegetable and flower gardens, landscaped areas, lawns, in the vicinity of small fruit and fruit trees, around and on buildings, sidewalks, fences, bark mulch, driveways, patios and gravel Mitigating statement for lawns added: "When spot treating individual weeds in lawns, avoid spraying the surrounding grass (lawn) as injury will occur."	None
For use on moss, algae, liverworts, and lichens around and on buildings, roofs, decks, sidewalks, fences, bark mulch, hardened bark of trees, driveways, patios and gravel	For use on moss and algae around and on buildings, roofs, decks, sidewalks, fences, bark mulch, driveways, patios and gravel	No data to support use on liverworts and lichens No data to support use on hardened bark of trees

References

A. LIST OF STUDIES/INFORMATION SUBMITTED BY REGISTRANT

1.0 Chemistry

PMRA Document Number	Reference
1280517	2006, Binder 2 Part 2 Chemistry Requirements, DACO: 2.0, 2.1, 2.11, 2.11.1, 2.11.2, 2.11.3, 2.11.4, 2.12, 2.12.1, 2.12.2, 2.13, 2.13.1, 2.13.2, 2.13.3, 2.13.4, 2.14, 2.14.1, 2.14.10, 2.14.11, 2.14.12, 2.14.13, 2.14.14, 2.14.2, 2.14.3, 2.14.4, 2.14.5, 2.14.6, 2.14.7, 2
1280518	2006, CBI Reference Document to Binder 2, DACO: 2.11.2, 2.11.3, 2.12.1 CBI
1280519	2005, Storage Stability of NEU1170H SL, DACO: 2.14.14
1406267	2007, Revised Binder 2 RTU, DACO: 2.0, 2.1, 2.10, 2.11, 2.11.1, 2.11.2, 2.11.3, 2.11.4, 2.12, 2.12.1, 2.12.2, 2.13, 2.13.1, 2.13.2, 2.13.3, 2.13.4, 2.14, 2.14.1, 2.14.10, 2.14.11, 2.14.12, 2.14.13, 2.14.14, 2.14.2, 2.14.3, 2.14.4, 2.14.5, 2.14.6, 2.14.7, 2.14.8, 2.14.9
1286764	2006, Binder #2 Part 3 Product Chemistry, Binder #2, MRID: 444830-01, 444830-02, 444830-03, DACO: 3.0, 3.1, 3.1.1, 3.1.2, 3.1.3, 3.1.4, 3.2, 3.2.1, 3.2.2, 3.2.3, 3.3.1, 3.3.2, 3.4, 3.4.1, 3.4.2, 3.5, 3.5.1, 3.5.10, 3.5.11, 3.5.12, 3.5.13, 3.5.14, 3.5.15, 3.5.2, 3.5.3, 3.5.4, 3.5
1286765	2002, Storage Stability of NEU1170H, NEU1170-990409, DACO: 3.5.10
1286766	1998, Product Chemistry Review of EP, DACO: 3.7
1404858	2007, Revised Binder 2 Concentrate, DACO: 3.0, 3.1, 3.1.1, 3.1.2, 3.1.3, 3.1.4, 3.2, 3.2.1, 3.2.2, 3.2.3, 3.3.1, 3.3.2, 3.4, 3.4.1, 3.4.2, 3.5, 3.5.1, 3.5.10, 3.5.11, 3.5.12, 3.5.13, 3.5.14, 3.5.15, 3.5.2, 3.5.3, 3.5.4, 3.5.5, 3.5.6, 3.5.7, 3.5.8, 3.5.9, 3.7
1286829	2006, Binder #2 Part 3 Product Chemistry, Binder #2, MRID: 443656-01, 443656-02, 443656-03, DACO: 3.0, 3.1, 3.1.1, 3.1.2, 3.1.3, 3.1.4, 3.2, 3.2.1, 3.2.2, 3.2.3, 3.3.1, 3.3.2, 3.4, 3.4.1, 3.4.2, 3.5, 3.5.1, 3.5.10, 3.5.11, 3.5.12, 3.5.13, 3.5.14, 3.5.15, 3.5.2, 3.5.3, 3.5.4, 3.5
1286830	2006, CBI Reference Document to Binder 2, CBI to Binder 2, MRID: 443656-01, 443656-02, DACO: 3.2.1, 3.2.2, 3.3.1 CBI

1286831 2002, Storage Stability of NEU1170H RTU, NEU1170RTU 96-923, DACO: 3.5.10

1286832 1998, Product Chemistry Review of EP, DACO: 3.7

1404870 2007, Revised Binder 2 RTU, DACO: 3.0, 3.1, 3.1.1, 3.1.2, 3.1.3, 3.1.4, 3.2, 3.2.1, 3.2.2, 3.2.3, 3.3.1, 3.3.2, 3.4, 3.4.1, 3.4.2, 3.5, 3.5.1, 3.5.10, 3.5.11, 3.5.12, 3.5.13, 3.5.14, 3.5.15, 3.5.2, 3.5.3, 3.5.4, 3.5.5, 3.5.6, 3.5.7, 3.5.8, 3.5.9, 3.7

2.0 Impact on Human and Animal Health

PMRA Document Number	Reference
1280521	Assessment of Acute Oral Toxicity with NEU 1170 H in the Rat. Report number: 197009. NOTOX Project 197009. DACO 4.2.1
1280522	Assessment of Acute Dermal Toxicity with NEU 1170 H in the Rat. Report number: 197011. NOTOX Project 197011. DACO 4.2.2
1280523	4-Hour Acute Inhalation Toxicity Study with NEU 1170 H in Rats. Report number: 97 10 42 026. DACO 4.2.3
1280524	NEU 1170 H 21% Acute Eye Irritation/Corrosion- First Amendment. Report number: 97 10 42 803 B. DACO 4.2.4
1280525	NEU 1170 H 22%ig Acute Eye Irritation/Corrosion- Second Amendment. Report number: 97 10 42 803 B. DACO 4.2.4
1280526	Acute Eye Irritation/Corrosion NEU 1170 H 21%. Report number: 97 10 42 803 B. DACO 4.2.4
1280528	Acute Dermal Irritation/Corrosion NEU 1170 H 21% ig. Report number: 97 10 42 803 A. DACO 4.2.5
1280529	Assessment of Contact Hypersensitivity to NEU 1170 H in the Albino Guinea Pig (Maximisation-Test). Report number: 274591. NOTOX Project 274591. DACO 4.2.6
1286838	Acute Eye Irritation/Corrosion Study with NEU 1170 H RTU in the Rabbit. Report number: 207934. DACO 4.6.4.
1286842	Primary Skin Irritation/Corrosion Study with NEU 1170 H RTU in the Rabbit (4-Hours Semi-Occulusive Application). Report number: 207934. Project 207923. DACO 4.6.5

3.0 Impact on the Environment

PMRA Document Number	Reference
1280533	2006, Binder 5 Part 8 Environmental Chemistry and Fate, DACO: 8.1, 8.2, 8.2.1, 8.2.2, 8.2.2.1, 8.2.2.2, 8.2.2.3, 8.2.2.4, 8.2.3, 8.2.3.1, 8.2.3.2, 8.2.3.3, 8.2.3.3.1, 8.2.3.3.2, 8.2.3.3.3, 8.2.3.4, 8.2.3.4.2, 8.2.3.4.4, 8.2.3.5, 8.2.3.5.2, 8.2.3.5.4, 8.2.3.5.6, 8
1280534	1990, Testing the biological degradability of Neudosan in two soils, DACO: 8.2.3.4.2
1280535	2002, Ready Biodegradability of Pelargonic Acid in a Manometric Respirometry Test, 14737160, DACO: 8.2.3.4.2
1280536	2006, Binder 6 Part 9 Environmental Toxicology, DACO: 9.1, 9.2, 9.2.1, 9.2.3, 9.2.4, 9.2.4.1, 9.2.4.2, 9.2.4.3, 9.2.5, 9.2.6, 9.2.7, 9.3, 9.3.1, 9.3.2, 9.3.3, 9.4, 9.4.1, 9.5, 9.5.1, 9.5.2, 9.5.2.1, 9.5.2.2, 9.5.3, 9.5.3.1, 9.6, 9.6.1, 9.6.2, 9.6.2.1, 9.6.2.4, 9.6.2.5, 9
1280537	1998, Acute Toxicity of NEU1170H on Earthworms, *Eisenia foetida*, Using an Artificial Soil Test, 97253/01-NLEf, DACO: 9.2.3
1280538	1998, Assessment of Side Effects of NEU1170H to the Honey Bee, *Apis mellifera* L. in the Laboratory, 97253/01-BLEU, DACO: 9.2.4.1, 9.2.4.2
1280539	1998, Acute Immobilization Test Daphnia - *Daphnia magna*, 98 10 48 039, DACO: 9.3.2
1280540	1999, Acute Toxicity Testing of NEU1170H in Rainbow trout (*Oncorhynchus mykiss*), 99024/01-AAOm, DACO: 9.5.2.1
1280541	1999, Acute Toxicity Testing of NEU1170H in Golden Ite (*Leuciscus idus*), 99024/01-AALi, DACO: 9.5.2.2
1280542	1999, 28-Day prolonged toxicity test of NEU1170H in Rainbow Trout (*Oncorhynchus mykiss*), 99024/01-ACOm, DACO: 9.5.3.1
1280543	1997, 5-Day Dietaryl Toxicity Study in Bobwhite Quail with Neudosan NEU, 185085, DACO: 9.6.2.1
1280544	1996, Acute Oral Toxicity Study in Bobwhite Quail with Neudosan NEU, 185052, DACO: 9.6.2.1

1280545 2003, Avian Dietary Toxicity Test of NEU1170H in the Japanese Quail, 10-16-0146-03, DACO: 9.6.2.4

1280546 1997, 5-Day Dietary Toxicity Study in Bobwhite Quail with Neudosan NEU, 185118, DACO: 9.6.2.5

1280547 1999, Algae Growth Inhibition Test *Scenedesmus subspicatus*, 98 10 48 040, DACO: 9.8.2

1280548 1999, Testing of Toxic Effects of NEU1170H on the Blue-Green Alga *Anabaena flos-aquae*, 99024/01-AAAf, DACO: 9.8.2

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4.0 Value

PMRA Document Number	Reference
1280506	Low Risk Rationale Finalsan TGAI
1286754	Binder 4-Value
1286756	Herbicidal Activity of Non-Selective Weed Killers
1286757	Herbicidal Activity of Non-Selective Weed Killers
1286756	Herbicide Trial
1286759	Efficacy of NEU1170H and NEU1170H AF to control mono- and dicotyledonous weeds, mosses and algae on paths and open areas with tree growth, mono- and dicotyledonous weeds in ornamentals and mosses in lawns
1565978	Annex IIIA data
1280518	CBI Reference Document to Binder 2
1406268	Binder #5-Addendum
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B. ADDITIONAL INFORMATION CONSIDERED

i) Published Information

1.0 Impact on Human and Animal Health

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ii) List of Unpublished Information Considered

1.0 Impact on the Environment

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